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**From:** Shams, Dahnish [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B7037E39BB6341C8850BCDC61BF9D65A-SHAMS, DAHN]  
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**Subject:** News Update: NAS Advice Opens Door To New EPA Debate Over Controversial Risk Ranges (Inside EPA)

## NAS Advice Opens Door To New EPA Debate Over Controversial Risk Ranges

Posted: May 23, 2014

EPA officials are preparing to discuss how they might address recent National Academy of Sciences (NAS) advice to improve the influential Integrated Risk Information System (IRIS) program, including consideration of the use of controversial risk ranges, rather than single point estimates, as a way to account for scientific uncertainties.

But the agency's consideration of the advice could be controversial -- just as it was when EPA's Bush-era research chief George Gray pushed the approach -- because some staff fear that quantifying uncertainty is resource intensive while adopting risk ranges will

undercut protective risk management standards and create difficulties for regulators that rely on the single point risk estimates to justify their decisions.

The idea of presenting uncertainty around the single point estimate risk values contained in IRIS documents remains a long-standing sore point for some, who argue that such numbers do not reflect the reality of uncertainties and variabilities inherent in assessing the toxicity of environmental contaminants, often with limited data.

NAS' May 6 report, "Review of EPA's [IRIS] Process," is the latest from the academy to recommend that the IRIS program should address this uncertainty in its assessments, in part by including a range of risk estimates rather than a single point estimate.

During a May 5 conference call with reporters, Jonathan Samet, the NAS committee chairman, said that the committee, echoing recommendations in earlier NAS reports, recommends that "rather than bring forward a single number" IRIS assessments should include two dose-response values, "the traditional lower-bound estimate, and to show the range, provide a central estimate as well."

The report explains that "[r]eporting both values provides information on statistical uncertainty, such as sampling variation, and makes available to the risk assessor the full range of information."

Samet noted that EPA's draft IRIS handbook -- an effort started in response to NAS' critical 2011 review of the draft IRIS assessment of formaldehyde -- is incomplete. It does not yet contain a quantitative chapter discussing how IRIS assessors should calculate the toxicity values in the assessments. "That is the one missing piece of the draft handbook," he said. "We hope these recommendations will be helpful to them as they write" it.

The report also recommends that EPA seek peer review of the draft handbook, when completed.

NAS' latest recommendations on increasing the use of uncertainty analysis echoes similar calls in earlier NAS reports, such as the 2011 formaldehyde report, the 2009 "Science and Decisions: Advancing Risk Assessment" and a 2013 report from NAS' sister academy, the Institute of Medicine, "Environmental Decision-making in the Face of Uncertainty."

Ken Olden, director of EPA's National Center for Environmental Assessment, who leads the IRIS program, told members of a Science Advisory Board peer review panel during a May 22 conference call that the agency is planning to hold a public workshop next October to "focus on the recommendations made" in the latest NAS report. He said he is inviting members of the committee that wrote the report to participate in the workshop, and chair some of its individual sessions.

**The upcoming workshop could provide a venue for the debate over risk ranges**, much as it did during the Bush administration.

As President George W. Bush's last research chief, Gray argued the approach is more scientifically rigorous. He pressed for detailed uncertainty analysis and other cancer modeling changes to be conducted in one of several controversial assessments underway in the IRIS program at that time, including the assessment of the drycleaning solvent tetrachloroethylene (perc).

His efforts delayed release of the document two years, and Gray left office before the assessment was completed in 2012 -- without the comprehensive uncertainty analysis he had sought. NAS in its latest report on IRIS cited the perc IRIS assessment as an example of what it considered uncertainty analyses "conducted for select individual intermediate stages in the process (such as dose-response modeling and low-dose extrapolation), often in isolation from one another." The report acknowledges that such uncertainty analyses "have become more common in IRIS assessments."

But EPA sources, environmentalists and others expressed misgivings about the approach. Using ranges instead of single point estimates in IRIS "will mean that providing consistency across decisions, programs, sites and standards will be an enormous challenge," one EPA staffer said at the time.

For example, the source warned it could create avenues for softening EPA safety standards for toxics. "This will make it harder for EPA regulators to draw a consistent line in the sand about acceptable exposures" at cleanup sites and when addressing other public health threats.

But long-time proponents of uncertainty analysis have been renewing their calls for EPA to expand its adoption, even before issuance of the latest NAS report.

For example, Sen. David Vitter (R-LA), the ranking Republican on the Senate environment committee, asked Thomas Burke, President Obama's nominee to serve as EPA research chief, whether he would commit to following White House guidance documents that require disclosure of uncertainties.

In written questions to Burke following his December 2013 confirmation hearing, Vitter notes that the Office of Management & Budget (OMB)'s Circular A-4 guidance "requires key uncertainties to be disclosed and quantified to the extent possible to inform decision

makers and the public about the effects and uncertainties of alternative regulatory decisions. However, EPA has a practice of excluding and failing to quantify key uncertainties in the cost-benefit analysis of rulemakings."

He asked Burke generally if he would commit to following all OMB circulars and guidance and asked specifically "How will you ensure that key uncertainties are included and quantified in the cost-benefit analysis of EPA rulemakings?"

Burke replied Jan. 17 that while not familiar with the "specific requirements" of Circular A-4 guidance, if confirmed he would "commit to follow all applicable OMB circulars and guidelines and to support the broader agency's efforts to comply with any such requirements."

**But consideration of the approach is already prompting concerns from some agency sources**, who suggest that one of the pressures against producing IRIS ranges instead of a single number may be regional and program offices that use the IRIS documents to set clean up standards and make other decisions.

"It's easier, if I have a number, versus a range," to make those decisions, one agency source says, adding that a range "puts the responsibility someplace else. We all would like a number." The source said that IRIS leadership would need input and buy-in from leaders in other agency program offices before such an approach could be adopted. A range, the source says, "puts a little more pressure on the folks" in the program offices.

A second agency source also noted the problems a risk range presents for program offices and their risk managers, asking rhetorically, when presented with a range for a cleanup level, "What community is going to be happy with the high" end of the range?

The first source, however, says that IRIS leaders should consider the recommendation, adding that risk ranges will make the jobs of IRIS assessors "easier and more accurate" because they "don't know if it's this number or that number. It would be better to communicate a range."

The issue is not unique to IRIS. During discussions of how to present risk estimates from IRIS and other regulatory agencies to decision makers at the May 21 Alliance for Risk Assessment Beyond "Science and Decisions" conference, a Texas Commission on Environmental Quality (TCEQ) toxicologist was asked about his interaction with TCEQ risk managers. "Usually they just ask, 'What's the number?'" said Mike Honeycutt, a TCEQ toxicologist and risk assessor. "Some do like to get into the details." -- *Maria Hegstad*

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